

Inc., New York, NY, 1939; (a) p. 270; (b) p. 272.

5. Cooperative agreements for community-based demonstration project for acquired immunodeficiency syndrome (AIDS) prevention and risk reduction and innovative projects for AIDS risk reduction; availability of funds for fiscal year 1985. Federal Register 50: 30298-30300, No. 143, July 25, 1985.
6. Program announcement and notice of availability of funds for fiscal year 1986; cooperative agreements for acquired immunodeficiency syndrome (AIDS); health education and risk reduction programs. Federal Register 51: 3427-3433, No. 17, Jan. 27, 1986.
7. Update: Acquired immunodeficiency syndrome—United States. MMWR 35: 17-21, Jan. 17, 1986.
8. Program announcement and availability of funds for fiscal year 1987 for cooperative agreements; acquired immunodeficiency syndrome (AIDS) prevention projects. Federal Register 52: 7028-7035, No. 44, Mar. 6, 1987.
9. Supplemental funds available for fiscal year 1987; cooperative agreements for acquired immunodeficiency syndrome (AIDS) prevention projects. Federal Register 52: 29438-29439, No. 152, Aug. 7, 1987.
10. Cooperative agreements for acquired immunodeficiency syndrome (AIDS) prevention and surveillance projects program announcement and notice of availability of funds for fiscal year 1988. Federal Register 53: 3554-3558, No. 24, Feb. 5, 1988.
11. Cooperative agreements for minority and other community-based human immunodeficiency virus (HIV) prevention projects program announcement and availability of funds for fiscal year 1989. Federal Register 54: 663-667, No. 5, Jan. 9, 1989.
12. Cooperative agreements for minority community-based human immunodeficiency virus (HIV) prevention projects. Federal Register 54: 46649-46651, No. 213, Nov. 6, 1989.

Evaluating the CDC Program for HIV Counseling and Testing

DEBORAH L. RUGG, PhD
ROBIN J. MacGOWAN, MPH
KATHLEEN A. STARK
NANCY M. SWANSON, PhD

Three of the authors are with the Public Health Service's Centers for Disease Control. Dr. Rugg is Chief of the Evaluation Research Section, National Center for Chronic Disease Prevention and Health Promotion. Mr. MacGowan and Ms. Stark are with the National Center for Prevention Services. Dr. Swanson is with Providence Hospital, Inc., Holyoke, MA.

A version of this paper was presented at the Assessing AIDS Prevention International Conference, Montreux, Switzerland, October 29-November 1, 1990, and at the World Health Organization's Global Programme on AIDS, Consultation on the Assessment of Counselling Efficacy in HIV/AIDS, Geneva, Switzerland, November 13-16, 1990.

Tearsheet requests to Deborah Rugg, PhD, at CDC, NCCDPHP, MS K33, Atlanta, GA 30333.

Synopsis

The Centers for Disease Control is conducting two investigations of the outcomes of HIV counseling and testing services offered persons at high risk for infection with the human immunodeficiency virus (HIV). One investigation is a trial conducted

at sexually transmitted disease clinics where an enhanced version of HIV counseling and testing is compared with a standard version. The other investigation is a longitudinal study of the effects of HIV counseling and testing in drug treatment programs that use methadone therapy.

In the evaluation, comparisons are being made of different ways of offering HIV counseling and testing and of the effectiveness of the program among persons who know their HIV serostatus and those who do not. The outcome variables include self-reported sexual and drug-using behaviors, together with corroborating laboratory tests, drug treatment compliance, mental health effects, and services utilization. Methodological, practical, and sociopolitical challenges were encountered in the evaluations. Possible solutions to the problems are described.

The authors conclude that the designs of the evaluations were appropriate, but that considerable resources are required to carry them out. In settings with low levels of resources, thorough evaluation of the process and an assessment of the immediate outcomes may be the most appropriate evaluation strategy. As HIV counseling and testing are of fundamental importance to national and international HIV prevention efforts, their evaluation is a critical issue.

THE ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA), which detects antibodies to the human

immunodeficiency virus (HIV), was licensed in 1985 and first used in screening the blood supply,

permitting positive or reactive units of blood to be discarded or put aside to be used for research purposes.

Because the demand for testing persons at high risk for HIV infection was expected to overburden blood donation centers, unless other testing sites became available, a nationwide Alternate Test Site (ATS) Program was initiated by the States, with guidance from the Centers for Disease Control (CDC), and with State and Federal support. As the volume of testing increased, blood donation centers, CDC, and others recognized the need to provide those being tested with free test-linked counseling. The ATS HIV counseling and testing program subsequently became a key component of national activities to prevent HIV infection and acquired immunodeficiency syndrome (AIDS).

Counselors at the sites were called upon to explain to those being tested the meaning of HIV test results, including the possibility of false positive or false negative results. However, as the program grew, State legislatures began to pass laws to require mandatory reporting of persons found to be HIV seropositive, and controversy developed over the purpose and value of the testing.

In response, some organizations began to emphasize the importance of a program that included HIV risk-reduction counseling preceding the HIV antibody test, called pretest counseling, and counseling following testing, called posttest counseling. The initial objectives of pretest counseling were to provide basic information on HIV prevention, to conduct risk assessments to assess the appropriateness of the test for those requesting testing, and to describe the limitations of the test and verify that the persons who requested the test still wanted to be tested. The purposes of posttest counseling were to inform the clients of the test results, to offer emotional support, and to refer those who tested positive to followup medical and support services.

In 1987 the new emphasis placed on risk-reduction counseling led CDC to rename the intervention, calling it HIV counseling and testing, and to rename the ATSS, calling them HIV Counseling and Testing Sites (CTS). The objectives were reformulated to "help uninfected individuals initiate and sustain behavioral changes that reduce their risk of becoming infected and to assist infected individuals in avoiding infecting others." (1)

By the end of 1989, with the introduction of antiviral agents such as zidovudine (AZT), new emphasis was placed on early detection of HIV infection and referral of infected individuals to

early therapeutic intervention and medical monitoring. Once again the focus changed, from HIV counseling and testing for behavior change to testing for purposes of early detection. This shift was supported by the fact that, at the time, no formal evaluations were available to demonstrate the effectiveness of CDC-defined HIV counseling and testing in facilitating behavior change.

New interventions, such as HIV counseling and testing, require evaluation research to determine their effectiveness. CDC has been examining the effectiveness of HIV counseling and testing using both process and outcome measures. Process evaluation provides information on the quantity of services and the characteristics of those served, on the quality of the program implementation, and on changes in the delivery of the intervention. Outcome evaluation determines the effectiveness of the intervention, for whom it is effective, and under what conditions. These complementary approaches to evaluation are necessary to ensure appropriate use of resources and to assess whether the intervention is having the desired effects on the intended population groups.

By September 1989, HIV counseling and testing was provided in more than 5,000 sites nationwide (2). By the end of 1990, CDC was spending nearly \$100 million per year to provide this service, and more than 2.6 million tests had been performed at publicly funded testing sites (3). By mid-1990, rigorous studies assessing the effectiveness of HIV counseling and testing were underway.

Theoretical Considerations

There is little theoretical basis for believing that the basic pretest (lasting 2 to 20 minutes) and posttest (lasting 20 to 30 minutes) counseling intervention alone could achieve the objectives of behavior change, without other conditions being present. HIV counseling and testing is primarily an information dissemination intervention, loosely based on a rational decision-making model, in which knowledge of the potential negative consequences of one's behavior is seen as sufficient to influence that person's behavior (4).

HIV counseling and testing is likely to be only one component of an effective program to influence behavior change on a large scale. A variety of predisposing factors are essential to influence changes in difficult-to-modify behaviors. These factors include a person's readiness to change (5), perceived self-efficacy (that is, perceived ability to make the necessary change) (6), perceived norms

regarding the behavior to be changed (7), and personal and interpersonal skills (8). CDC is examining the effects of current approaches to HIV counseling and testing, and is measuring some of the predisposing factors to find ways to improve current interventions.

CDC Evaluation Study Designs

HIV counseling and testing has become a standard clinical practice in HIV prevention efforts. CDC has recommended that HIV counseling and testing be provided in a variety of settings to persons seeking testing or at risk of HIV infection (1). Thus, the random assignment of persons to an intervention control group is not possible. Experimental studies are limited to designs that compare different levels of counseling intensity.

Additional problems exist in disentangling the effects of HIV counseling from the effects of knowing one's serostatus, since HIV counseling should always be provided with HIV testing (1). Thus, the effectiveness of either component alone ethically cannot be determined (9).

The soundest evaluation designs are limited to determining differential effectiveness; that is, identifying what works better. The following is an overview of two of CDC's HIV counseling and testing studies.

Quantitative component. To evaluate the effectiveness of HIV counseling and testing, two studies were designed. One examined patients of a sexually transmitted disease (STD) clinic; this study currently is in the pilot phase. The other, a longitudinal study of drug treatment programs that use methadone therapy, has been collecting data since mid 1990, and will continue until December 1992.

STD clinic study. In the STD clinic study, an experimental design is used in which half of the subjects are randomly assigned to standard HIV counseling and testing, and half are assigned to a multiple-session, skills-based enhanced counseling intervention. This design tests whether the enhanced intervention is more effective in facilitating risk behavior change than the standard HIV counseling and testing.

Methadone therapy study. In the methadone treatment program, random assignment of participants to different levels of HIV counseling and testing was not possible. Therefore, a nonexperimental, longitudinal design having two naturally

occurring treatment conditions was used. Data are obtained from baseline and multiple postintervention observations at 1, 3, 6, and 12 months. The participating sites are geographically proximate and demographically similar in clientele, but differ in how they offer HIV counseling and testing.

In condition 1, the program initiates and encourages HIV counseling and testing in a routine manner when the client enrolls in the program. The client does not need either to be motivated or actively seek the test (program-initiated testing).

In condition 2, HIV counseling and testing, although available, is not incorporated into the intake process of the program. The client needs to be motivated enough to actively seek HIV counseling and testing (client-initiated testing).

These studies will examine the effect of different approaches to HIV counseling and testing on test-seeking and sexual and drug-using behavior, as well as on mental health indicators, program compliance, and utilization of HIV-related services. Differences between those who know they are seropositive or seronegative and those who are unaware of their serostatus will be examined.

Qualitative component. Qualitative or ethnographic data are collected in both studies. In the STD clinic, focus groups and key informant interviews are used in developing the intervention content. In the longitudinal study in methadone clinics, a more indepth ethnographic component has been included; ethnographers at each site periodically conduct process evaluations and monitor the impact of the intervention on clients and the methadone treatment staff, and on program procedures.

Descriptions of each program's HIV counseling and testing intervention were developed through direct observation of the intervention, a review of written documents, and open-ended and semi-structured interviews with administrators, staff members, and clients. A sampling frame for interviews and observations was developed to ensure that comparable data were gathered in each research site, and that the data were representative of events, behaviors, and interactions at each site.

The interviewers who administered the quantitative instrument to study participants were trained to record supplementary qualitative data that were volunteered by clients during the interview. The client-generated data include marginal comments pertaining to individual questions in the study, explanations offered by clients for their risk-taking behaviors, information about the social context of clients' drug-use behaviors, and clients' comments

concerning their participation in HIV counseling and testing and in the study. Qualitative data will be transcribed into a computerized text-based format and analyzed using the ETHNOGRAPH computer program throughout the next 2 years of the study (A).

This information will help in interpreting the outcome data, especially in the event of counter-intuitive findings, and in monitoring the program so that an accurate description of the intervention can be made and the effects of HIV counseling and testing on the methadone treatment program itself can be considered.

Evaluation Challenges and Solutions

There are numerous methodological challenges in evaluating a variety of HIV prevention programs (10). The following are some of the most important issues encountered by CDC in evaluating HIV counseling and testing.

Intervention variation issues. The implementation of HIV counseling and testing is known to vary dramatically by

- the site, depending on State and local policies, program philosophies, procedures, and content;
- the counselor, depending on his or her training, qualifications, attitudes, and client load;
- the client, depending on past testing history, serostatus, risk behavior, demographic characteristics, and real or perceived needs;
- the geographic location; and
- the historical context of the intervention as HIV prevention recommendations are refined.

The first steps in the evaluation were to describe the intervention; to determine intervention objectives; and to assess their appropriateness, specificity, measurability, the degree to which they were time-phased, and their theoretical or conceptual basis.

Specifying the objectives made it possible to define the expected outcomes and the research questions to be answered by the results of the evaluation.

Sample size issues. The sample size must be large enough to detect intervention effects. In the longitudinal study, an estimated 500 subjects must be enrolled in each of the two conditions to yield a minimum sample size of 270, which would provide sufficient power in the study to detect differences

'In low-resource settings, process evaluation and an examination of the immediate effects of HIV counseling and testing may be the appropriate strategy.'

between the 2 conditions by the end of 1 year. Participants were recruited from five sites to obtain the total sample of 1,000.

Recruiting and retention. To enhance study recruiting and retention in the methadone clinic study, participants are paid \$100 for completing five interviews. Because of this, they are more likely to remain in the study throughout the 12 months. They are actively tracked if they drop out of the drug treatment program during this time. Child care is provided parents while they are at the clinic. This factor has aided in creating a trusting relationship between participants and interviewers. As a result, participants are encouraging other methadone clients to become involved in the study. Currently, a 75 percent participation rate and a retention rate of 99 percent at the 1- and 3-month followups are being obtained. The population of 270 clients is 45 percent white, 27 percent Hispanic, 22 percent black, 6 percent other racial or ethnic minorities, and 59 percent male.

Sources of bias. A variety of potential sources of bias were considered. These include

- recall bias, when a respondent has difficulty remembering past events accurately;
- social desirability bias, when a respondent provides answers he or she believes to be socially appropriate;
- situational demand bias, when the respondent provides responses based on the nature of the situation; and
- selection bias, owing to volunteerism or motivational differences, such as differences in individual motivation to alter risk.

Those who are ready to make changes in their risk behavior may be systematically more likely to obtain HIV counseling and testing than those who are less motivated and less likely to change. This could create bias in the sample towards those who would have made changes regardless of exposure to the intervention. This bias makes it difficult to

determine whether observed changes resulted from the intervention or predisposing individual characteristics. Such persons have an increased likelihood of participating in studies. Persons need to be motivated sufficiently to voluntarily seek HIV counseling and testing and may require prerequisite abilities and readiness-to-change for HIV counseling and testing to be effective. Without a randomized control group, this potential bias is difficult to control or further elucidate.

This problem will be examined indirectly by comparing risk behaviors, adjusting for serostatus, of those who actively seek testing, those who accept testing, those who actively refuse testing, or those who do not seek testing. To accomplish this, clients who had never been tested for HIV were enrolled into the study.

Sources of confounding. Persons exposed to HIV counseling and testing are exposed to a variety of confounding influences. Such influences include other HIV prevention interventions, as well as variations in individual behavior patterns, population trends, historical events, geographic variations, and ceiling effects (when, because of behavior changes already made, there is little room for additional changes resulting from the intervention to be detected).

The effects of some of these issues can be minimized by using a longitudinal cohort design with multiple baselines and postintervention observations and matched comparison groups. Other potential confounders in the methadone clinic study (for example, race or ethnicity, past test history, duration in drug treatment, methadone dosage, degree of utilization of other services, and codependence on cocaine or alcohol) will be analyzed as covariates.

Measurement. Outcome measures need to be clearly linked to intervention objectives, taking into consideration the purpose of the study, the ease with which such outcomes can be measured and obtained, and the appropriateness of the measure for the target population. In the methadone clinic study, an examination of these issues during an 8-month pilot phase led to considerable refinement of the outcome measures. A tailored evaluation instrument was developed for the methadone treatment population, although some core behavioral items were taken from other standardized CDC questionnaires.

HIV seroincidence is not a sufficiently sensitive outcome measure because of the low frequency of

seroconversions. Persons engaging in high-risk behaviors may not seroconvert during the course of the evaluation; those who do seroconvert may have been infected prior to the study. As the National Academy of Sciences report (9) concludes, seroincidence is not a useful outcome indicator of the effectiveness of HIV counseling and testing for seropositive persons because they may have previously seroconverted. However, important behavioral change objectives remain for this population. Outcome measures obtained in the CDC evaluation studies include self-reported sexual and drug-using behaviors, supplemented by laboratory measures of STDs and urine tests for drugs, and clinic record information. In these studies, self-reported behavior, laboratory tests, and clinic record data are linked and analyzed before conclusions are drawn.

People can recall sexual and drug-using behaviors for varying periods, but recall of the specifics of such behaviors is dulled by time (11). Therefore, in these studies, participants are asked to recall their behaviors during the last 30 days at each assessment. To help study participants accurately recall their risk-related behaviors, interviewers were trained to use memory elicitation techniques, including the use of calendars to help anchor past events and behaviors.

Outcomes should be assessed when the intervention is believed to have had its effect. Short-term effects of HIV counseling and testing are expected to be observed in the period from the first 2 days to 1 month. In the longitudinal study, participants are interviewed at baseline and within 2 to 4 weeks after notification of test results in order to identify short-term effects on risk behaviors, mental health, drug treatment compliance, and services utilization. Participants are interviewed again at 3, 6, and 12 months to determine the long-term effect on these variables.

Sociopolitical Issues

As local, State, national, and international agencies faced the question of the efficacy of their HIV prevention programs, several fundamental issues emerged. For example, the terms *evaluation* and *counseling* both have very different meanings to different people, which makes communication on these topics difficult. Further, the differing agendas of researchers, program managers, and politicians in emotionally charged environments influence HIV counseling and testing evaluation efforts. Thus, it is necessary to be flexible and creative when confronting these unavoidable barriers.

Most agencies lack sufficient resources to conduct rigorous evaluations. Determining efficacy is a long-term and resource-intensive process. This process can create problems for those who may need immediate answers.

Finally, expectations of what an evaluation will show may be unrealistic. Allowing sufficient time for the development of shared expectations, with frequent communication, will help to minimize the effects of these larger context issues.

Conclusion

This article outlines some of the major historical, practical, methodological, and sociopolitical obstacles facing HIV counseling and testing evaluators. We have described how CDC is attempting to combine quantitative and qualitative methodologies to achieve an accommodation between these constraints and the ideal.

CDC is conducting a randomized, controlled trial examining different levels of HIV counseling interventions. Where use of this design was not possible, a longitudinal study design was implemented that includes multiple baseline and postintervention observations, appropriate comparison groups, and a careful consideration of covariates.

Such evaluation strategies take considerable resources and may not be feasible in many low-resource settings. Repeated cross-sectional surveys may be more feasible. However, while simpler and faster, cross-sectional surveys require resources and will only determine the prevalence of behaviors, not the effectiveness of a specific intervention. In low-resource settings, process evaluation and an examination of the immediate effects of HIV counseling and testing may be the appropriate strategy. Before the true effectiveness of HIV counseling and testing can be determined, it is essential to ensure that the intervention has been designed to meet its objectives and that it has been implemented as intended (12).

HIV counseling and testing is a fundamental

component of current HIV prevention efforts in the United States and around the world (13). As such, HIV counseling and testing deserves our continued attention to improve the quality of this pivotal prevention strategy.

References

1. Public Health Service guidelines for counseling and antibody testing to prevent HIV infection and AIDS. *MMWR* 36: 509-515, Aug. 14, 1987.
2. Publicly-funded HIV counseling and testing—United States, 1985-1989. *MMWR* 39: 137-140, Mar. 9, 1990.
3. Centers for Disease Control: 1990 Division of STD/HIV Prevention annual report. Atlanta, GA, 1990.
4. Janis, I. L., and Mann, L.: *Decision making: a psychological analysis of conflict, choice and commitment*. Free Press, New York, NY, 1977.
5. Prochaska, J. O., and DiClemente, C. C.: Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 51: 390-395 (1983).
6. Bandura A.: Self-efficacy: toward a unifying theory of behavior change. *Psychol Rev* 84: 191-215 (1977).
7. Ajzen, I., and Fishbein, M.: *Understanding attitudes and predicting social behavior*. Prentice Hall, Englewood Cliffs, NJ, 1980.
8. Kelly, J. A., and St. Lawrence, J. F.: Behavioral intervention and AIDS. *Behav Therapist* 6: 121-125 (1986).
9. Coyle, S. L., Boruch, R. F., and Turner, C. F.: *Evaluating AIDS prevention programs*. National Academy Press, Washington, DC, 1989.
10. Rugg, D. L., O'Reilly, K. O., and Galavotti, C.: AIDS prevention evaluation: conceptual and methodological issues. *Evaluation and Program Planning* 13: 79-89 (1990).
11. Catania, J. A., et al.: Response bias in assessing sexual behaviors relevant to HIV transmission. *Evaluation and Program Planning* 13: 19-29 (1990).
12. Valdiserri, R. O.: *Preventing AIDS: the design of effective programs*. Rutgers University Press, Rutgers, NJ, 1989.
13. World Health Organization: *Guidelines for counseling about HIV infection and disease*. WHO AIDS Series 8, Global Programme on AIDS, Geneva, Switzerland, 1990.

Equipment

- A. Seidel, J. V., Kjolseth, R., and Seymour, E.: *The ETHNOGRAPH, Version 3.0*. Qualis Research Associates, Corvallis, OR, March 1990.